UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/464,414	12/16/99	THANAVALA	Y	RPP:156CUS

HM22/0411

DUNN & ASSOCIATES
P O BOX 96
NEWFANE NY 14108

EXAMINER	
FLOOD,M	
ART UNIT	**PAPER NUMBER**
1651	5

DATE MAILED: 04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/464,414	Thanavala
Examiner	**Group Art Unit**
Michele Flood	1651

☒ Responsive to communication(s) filed on *Dec 16, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-19* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-19* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 8 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is made vague and indefinite by the phrase "providing an immune response" because the meaning is unclear. Ambiguity exists in the identification of the process. In what way is an immune response provided in an animal? Is the claimed invention directed to a method of secondary immunization? The lack of clarity makes the claim indefinite.

Claim 1 is made vague and indefinite by the phrase "wherein the animal is made immunoreceptive to HBsAg" because it is unclear as to the meaning of the phrase. "Immunoreceptive" is not a term recognized in the art of immunology. In what way is an animal made immunoreceptive to an antigen? It is uncertain whether the animal was previously "made immunoreceptive" by other means of receiving immunity or whether the animal is "made immunoreceptive" by the method claimed in the invention of the applicant. The lack of clarity makes the claim indefinite.

Claim 1 is made vague and indefinite by the phrase "in an animal immunoreceptive to the NEPA" as it is uncertain whether the immune responsiveness of the animal is a preexisting condition or a newly required condition of immune responsiveness due to the feeding of the plant that contains the NEPA antigen. Ambiguity exists in the identification of the process. Thus, the lack of clarity makes the claim indefinite.

Claims 2 , 4 and 8 are made vague and indefinite by the abbreviation "HBsAg". Application may overcome the rejection by replacing the abbreviation "HBsAg" in line 1 of Claim 2, and in line 2 of claim 4 with the term hepatitis B surface antigen (HBSAG).

Claim 3 recites the limitation "pathogen" in line 5 of Claim 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 is made vague and indefinite by the abbreviation "NEPA". Applicant may overcome the rejection by replacing the abbreviation "NEPA" with the term non-enteric pathogen antigen.

Claim 3 is made vague and indefinite by the term "physiologically acceptable plant material containing an NEPA contained in the pathogen". Perhaps, Applicant can overcome the rejection by replacing the phrase "physiologically acceptable plant material containing an NEPA contained in the pathogen" with the phrase physiologically acceptable transgenic plant expressing recombinant immunogen derived from a non-enteric pathogen.

All of the claims are made vague and definite by the phrase "providing an immune response to a non-enteric pathogen antigen" in line 1 of Claim 1, by the phrase "where an animal

is immunoreceptive to the NEPA" in line 2 of Claim 1, and by the phrase "where the animal is made immunoreceptive to the NEPA" in line 4 of Claim 1 because there is no definite delineation among the meaning of the phrases. It is unclear as to Applicant's meaning of the phrases. Therefore, it is uncertain as to what subject matter Applicant regard as the invention.

Regarding, Claim 1, it appears that a step is the claimed process is missing because it is not apparent how the animal is "made immunoreceptive to the NEPA". Was the animal made immunoreceptive by exposure to the antigen via a contaminated biological material, such as blood or mother's milk? Or, was the animal made immunoreceptive to the NEPA by artificial immunization, such as parenteral administration of a vaccine? Any animal with a health immune system is "immunoreceptive" to a non-enteric pathogen antigen, if the animal is exposed in some manner to the antigen. Even in light of Applicant's definition of the terms, there appears no difference in the meaning of the terms "providing an immune response" or "made immunoreceptive", since "immunoreceptive" could mean the ability of an individual to demonstrate an immune response upon exposure to an antigen. Moreover, it is unclear whether there is any difference in Applicant's use of the terms "providing an immune response", "an animal made immunoreceptive", or "primary immunization", since none preclude each other and all encompass the scope of inducing or eliciting "a positive response to immunization".

Regarding Claims 16 and 17, the term "*solanaceae*" should be replaced with "*Solanaceae*".

Claim 19 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koprowski (A) in view of Stites (U).

Applicant claims a method for providing an immune response to a non-enteric pathogen antigen (NEPA), in an animal made immunoreceptive to the NEPA, by feeding the immunoreceptive animal with a substance comprising a physiologically acceptable plant material containing the NEPA where the animal is made immunoreceptive to the NEPA by immunization against a non-enteric pathogen containing the NEPA prior to feeding the animal the substance.

Koprowski teaches a process of providing an immune response in an animal or a human to a non-enteric pathogen, especially the non-enteric pathogen rabies street virus. In the process, a physiologically acceptable plant is genetically altered to express an antigen and used as an oral

delivery system to feed the animal or human a non-enteric pathogen antigen compound. Routes of administration in the delivery of the substance comprising the plant material containing the NEPA are taught in Column 5, lines 43-61. In Column 7, lines 18-31, Koprowski teaches viral, fungal, and bacterial pathogens which can be used against the invention. Koprowski does not teach a method wherein an animal made immunoreceptive to a non-enteric pathogen by immunization by feeding the immunoreceptive animal with a substance comprising a physiologically acceptable plant material containing the NEPA where the animal is made immunoreceptive to the NEPA by immunization against a non-enteric pathogen containing the NEPA prior to feeding the animal the substance. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional step to the process taught by Koprowski to induce an immune response in an immunized animal by feeding the immunized or immunoreceptive animal a substance containing the NEPA because the art recognizes the routine practice of inducing immunity or an immune response in an animal that has either passive immunity, acquired immunity or actively acquired immunity which is demonstrated by an antibody response that may or may not relate to specific immunity to infection or disease by vaccination or artificial immunization to provide or elicit an immune response. Moreover, Stites that reimmunization is a previously immune individual provides a rapid secondary increase in immunity. See page 724, Column 2, lines 1-42. Thus, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success that the feeding of an

animal with plant material containing a NEPA in an immunoreceptive animal would provide an immune response.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen (B) in view of Stites (U).

Applicant claims a method for providing an immune response to a non-enteric pathogen antigen (NEPA), in an animal or a human made immunoreceptive to the NEPA, by feeding the immunoreceptive animal with a substance comprising a physiologically acceptable plant material containing the NEPA where the animal is made immunoreceptive to the NEPA by immunization against a non-enteric pathogen containing the NEPA prior to the feeding the animal the substance. Applicant further claims a method where the NEPA is HBsAg.

Arntzen teaches an anti-viral vaccine produced in physiologically acceptable plants and then administered through standard vaccine procedure or by feeding the plants to an animal or human. Arntzen specifically teaches methods of making a transgenic plant expressing an immunogen derived from hepatitis B surface antigen, wherein the immunogen is capable of eliciting an immune response in an animal or a human by consumption of the said plant material. Arntzen also teaches methods of making a vaccine by recovering the immunogen expressed in the plant cell for use as a vaccine. Arntzen does not teach a method wherein an animal made immunoreceptive to a non-enteric pathogen by immunization by feeding the immunoreceptive

animal with a substance comprising a physiologically acceptable plant material containing the HBSAG where the animal is made immunoreceptive to the HBsAg by immunization against a non-enteric pathogen containing the HBSAG prior to feeding the animal the substance. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional step to the process taught by Arntzen to induce an immune response in an immunized animal by feeding the immunized or immunoreceptive animal a substance containing the HBSAG because the art recognizes the routine practice of inducing immunity or an immune response in an animal that has either passive immunity, acquired immunity or actively acquired immunity which is demonstrated by an antibody response that may or may not relate to specific immunity to infection or disease by vaccination or artificial immunization to provide or elicit an immune response. Moreover, Stites teaches that reimmunization in a previously immune individual provides a rapid secondary increase in immunity. See page 724, Column 2, lines 1-42. Thus, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success that the feeding of an animal with plant material containing a HBsAg in an immunoreceptive animal would provide an immune response.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 3, 5-7 and 9-19 are rejected under 35 U.S.C. as being unpatentable over Koprowski (A) in view of Stites (U).

Applicant claims a method for boosting an immune response to a non-enteric pathogen in a human previously having a positive response to immunization against the pathogen which method comprises the human ingesting a substance comprising a physiologically acceptable plant material containing an NEPA contained in the pathogen, and a therapeutic regimen thereof. Applicant further claims that the plant material is from a genetically altered plant.

Koprowski teaches a process of providing an immune response in an animal or a human to a non-enteric pathogen, especially the non-enteric pathogen rabies street virus. In the process, a physiologically acceptable plant is genetically altered to express an antigen and used as an oral delivery system to feed the animal or human a non-enteric pathogen antigen. Routes of administration in the delivery of the substance comprising the plant material containing the NEPA are taught in Column 5, lines 43-61. In Column 7, lines 18-31, Koprowski teaches other viral, fungal, and bacterial pathogens which can be used against the invention. Koprowski teaches, in Column 8, lines 24-31, plant-infecting microorganisms and solanaceous plant hosts, including potatoes. Koprowski does not teach a method for boosting an immune response to a non-enteric pathogen.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to induce a booster response in a human previously having an immune response to primary immunization against a non-enteric pathogen, wherein the method comprised the ingestion of plant material from a genetically altered plant containing a NEPA because Stites teaches on page 724, Column 2, lines 1-42, the principles of "booster" reimmunization in a

previously immune individual. One would have been motivated to optimize the teachings of Koprowski by inducing a secondary immune response in a human wherein the human ingests a genetically altered plant material expressing a non-enteric pathogen antigen, such as a solanaceous potato, because Stites teaches that reimmunization or a "booster shot" in a previously immune individual provides a rapid secondary increase in immunity. One would have had a reasonable level of success because Stites teaches that the timing of immunization, the interval between doses, and the timing of booster reimmunizations are based on both theoretic considerations and vaccine trials.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 3-19 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Arntzen (B)and Koprowski (A), and further in view of Stites et al. (U).

Applicant claims a method for boosting an immune response to a non-enteric pathogen in a human previously having a positive response to immunization against the pathogen which method comprises the human ingesting a substance comprising a physiologically acceptable plant material containing an hepatitis B surface antigen , and a therapeutic regimen thereof. Applicant further claims that the plant material is from a genetically altered plant.

The teachings of Arntzen and Koprowski are set forth above. Neither Arntzen nor Koprowski teach a method for boosting an immune response to hepatitis in a human.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to induce a booster response in a human having a positive response to primary immunization against hepatitis B surface antigen, wherein the method comprises the human ingesting a genetically altered potato containing hepatitis B surface antigen because Stites teaches on page 724, Column 2, lines 1-42, the principles of "booster" reimmunization in a previously immune individual. One would have been motivated to optimize the methods of oral immunization as taught by either Arntzen or Koprowski by inducing a secondary immune response in a human wherein the human ingests a genetically altered potato containing hepatitis B surface antigen, comprising a therapeutic regimen of ingesting the said plant material in a plurality of different times because Stites teaches, on page 724, lines 28-32, that the timing of primary immunization, the interval doses, and the timing of booster administrations are based on both theoretic considerations and vaccine administrations. One of ordinary skill in the art at the time the invention was made would have been motivated to use a genetically altered plant from the *Solanaceae* family because Koprowski expressly teaches, in Column 8, lines 24-31, solanaceous plants which are physiologically acceptable plant material that can be genetically altered and used in the delivery of oral vaccines for therapeutic purposes. Finally, it would have been obvious to use the methods and materials taught by Arntzen and/or Koprowski because the determination of an effective treatment method for boosting the immune response in a human to hepatitis B surface antigen previously having a positive response to primary immunization against hepatitis B which comprised the ingestion of genetically altered plant material containing hepatitis B surface antigen

would have been a matter of routine optimization to one of ordinary skill in the art at the time the invention was made.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Double Patenting

Claims 2, 4, 6, 8-15, 17 and 19 of this application conflict with claims 3-14 and 16 of Application No. 09/418,177 and Application No. 09/420,695. 37 CFR 1.78(b) provides that when two or more applications filed by the same applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 2, 4, 6, 8-15, 17 and 19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3-14 and 16 of copending Application No. 09/418,177 and 09/420,695.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 09/464,416. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are directed to the same subject matter, the scopes overlap and are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/418,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are directed to the same subject matter, the scopes overlap and are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/420,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are directed to the same subject matter, the scopes overlap and are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-4932. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

mcf

April 4, 2000

LEON B. LANKFORD, JR.
PRIMARY EXAMINER